II. REMARKS

A. Claim Amendments

Claims 1, 2, 5, 10, and 21-27 are pending, claims 3, 4, 6-9, and 11-20 having were canceled in previous amendments by Applicants.

Applicants propose to amend claims 1 and 21, as shown above, to add the phrase "so that a matrix coating on the pharmaceutical agent can be formed" to the characterization of the process used to produce the solid pharmaceutical dosage form of the invention. Support for this amendment can be found on page 4, line 30 of the application.

B. Rejection of Claims 1, 2, 5, 10, 21, and 22-27 Under 35 U.S.C. §103(a) Over EP552708 ('708) in View of U.S. 5,478,852 (Olefsky *et al.*)

Claims 1, 2, 5, 10, 21, and 22-27 were rejected under 35 U.S.C. §103(a) over '708 in view of Olefsky *et al.* '708 was described in the Office Action as teaching "a solid dispersion of a sparingly water-soluble drug made by mixing the drug and a water-soluble polymer at a temperature where neither is melted." The Office Action goes on to state that it would have been "obvious to one of ordinary skill to deliver the drug of Olefsky *et al* in the vehicle of '708 to achieve the beneficial effect of very high solubility and bioavailability."

The Manual of Patent Examination Procedure, (MPEP) states:

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA) 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." MPEP 2143.03 (8th ed. Rev. no. 4 Oct 2005)

Applicants respectfully submit that neither prior art reference nor the two references viewed together disclose a solid dosage comprising a solid particulate dispersion of a pharmaceutical agent in a matrix produced by mixing a pharmaceutical agent in crystalline form in a water-soluble polymer, "wherein the solid particulate dispersion is made by mixing the pharmaceutical agent and the polymer at a temperature sufficiently high to melt or soften the polymer, but insufficiently high to melt the pharmaceutical agent, so that a matrix coating on the pharmaceutical agent can be formed." (language common to claims 1 and 21, with amended language underlined)

'708 discloses a solid dispersion of a sparingly water-soluble drug in a water-soluble polymer. The specification of that published application states that the "heating temperature should be lower than the lower of the melting point of the sparingly water-soluble drug and that of the water-soluble polymer." ('708, p. 3, lines 23-24). The resulting dispersion is in the form of a powder. (*Id.* line 31). Nowhere does '708 teach or suggest melting or softening the water-soluble component of the dispersion to produce a matrix coating on the pharmaceutical agent. In fact, '708 indicates the solid dispersion taught by that reference is in the form of a powder, a powder wherein neither the sparingly soluble drug nor the water-soluble polymer have been melted.

The Office Action addresses the issue of the temperature teachings of '708 by stating that the temperature taught by '708 is within the temperature range of 50°- 200° C disclosed in the present application. However, Applicants respectfully submit that the temperature used to produce any given solid pharmaceutical dosage form of the present invention depends upon the respective melting temperatures of the pharmaceutical agent and water-soluble polymer components of the dispersion. When the pharmaceutical agent used in the solid particulate dispersion is troglizone, a compound with a melting point of 184-186°C, the agent and water-soluble polymer are mixed at a temperature below 184 °C, but sufficiently high to melt or soften the polymer. See, for example, page 9, lines 11-20. Applicants submit that '708 does not disclose or suggest producing a solid pharmaceutical dosage form by heating a dispersion of a pharmaceutical agent and water-soluble polymer at a temperature at which the polymer is softened or melted.

Olefsky *et al.* state that solid form preparations of troglizone and other pharmaceutical agents can be produced. Solid dosage forms disclosed include powders and tablets. However, nowhere does the reference teach or suggest the production of any solid particulate dispersion of a pharmaceutical agent in a matrix, much less a solid pharmaceutical dosage form of the present invention. Olefsky *et al.* fail to teach or suggest a solid pharmaceutical dosage form produced by a method with either of the two features described above: the mixing temperature; and the of melted or softened water-soluble polymer coating the pharmaceutical agent. Thus, neither Olefsky *et al.* nor '708, nor the two references viewed together disclose or suggest all the elements of claims 1 or 21. As all the remaining pending claims, 2, 5, 10, and 22-27 depend from either of those two independent claims, Applicants respectfully submit that the dependent claims are nonobvious for the same reasons as claims 1 and 21.

For reasons given above, Applicants submit that the claimed invention is not obvious over Olesky *et al.* Therefore, Applicants respectfully request that the rejection of claims 1, 2, 5, 10, and 21-27, under 35 U.S.C. §103(a) over '708 in view of Olefsky *et al.*, be withdrawn.

II. SUMMARY

Applicants respectfully request entry of all amendments herein. For reasons set forth above, Applicants respectfully submit that after amendment, all of the present pending claims (i.e., claims 1, 2, 5, 10 and 21-27) would be in condition for allowance. Issuance of all the claims is, requested. The Examiner is invited to contact the undersigned at the telephone number given below should he wish to discuss the present amendment and suggest additional changes to the claims in order to further prosecution of the application.

Dated: April 6, 2006

Karen B. King
Attorney for Applicants
Reg. No.: 41,898
Phone No.: (734) 622-4837